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EXAMINER

FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/563,688	Applicant(s) HOLLADAY, ROBERT J.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,18-24 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10,18-24 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/9/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendments/Remarks filed on October 9 2008 is acknowledged.

Claims 5, 11-17 and 25-34 were/stand cancelled. Claim 35 was amended. Claims 1-4, 6-10, 18-24 and 35 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 9 2008 was considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicant's arguments filed on October 9 2008 indicating that majority means that more than 50% of the particles have a maximum dimension of less than 0.015 micrometers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 8-10, 18-24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US Patent No. 20030054046, cited on PTO Form 1449).

Applicant Claims

Applicant claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver of between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide wherein the composition manifest antimicrobial properties.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Burrell et al. is directed to the treatment of inflammatory skin conditions. Example 11, number 2 discloses carboxymethyl cellulose (CMC) fiber coated directed with a nanocrystalline silver coating. The CMC was then gelled in water. The gel had significant bactericidal effect against *pseudomonas aeruginosa*. The silver utilized is

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similar to those set forth in Example 1. Example 1 discloses preparation of nanocrystalline silver coatings. The coating consists of a silver base layer and a silver oxide top layer (example 1). Example 11 (number 3) utilizes alginate as the hydrocolloid polymer. It is disclosed that the concentrations of silver in solution will vary but generally range from 1 to 5000 $\mu\text{g/ml}$ (1 to 5000 ppm) (paragraph 0054). The average grain size of example 1 is 10 nm. Silver containing gel (example 4) reduced pseudomonas aeruginosa and staphylococcus aureus properties (paragraph 0242). Other hydrocolloid polymers listed as being suitable include algal extracts, seed extracts, or plant exudates such as gum arabic, guar gum, alginates etc. (paragraph 0156). It is disclosed that other ingredients can be disclosed including surface active agents (surfactants) and growth factors (paragraph 0179). It is disclosed that the ethanol can be added to a silver containing dressing to activate the coating (paragraph 0183). Exemplified is the treatment of adult acne with silver gel occluded by a hydrocolloid dressing (example 12).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Burrell et al. does not exemplify a hydrogel with a concentration of silver from 5 to 40 parts per million. Burrell et al. do not exemplify utilizing a gum as the hydrocolloid polymer. Burrell et al. do not exemplify utilizing other anti-microbial agents or additives in addition to the silver. However Burrell et al. discloses that concentrations of silver utilized include 1 to 5000 ppm, that suitable hydrocolloids include gums such as guar gum, and that surfactants, growth factors or ethanol can be added to the composition.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to vary the amount of silver utilized in the hydrogel. One of ordinary skill in the art would have been motivated to utilize an amount of silver from 1 to 5000 ppm because these are the amounts disclosed by Burrell et al. as being suitable. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

It would have been obvious to one of ordinary skill in the art to utilize guar gum as the hydrocolloid polymer. One of ordinary skill in the art would have been motivated to utilize this polymer as it is disclosed a suitable hydrocolloid polymer to utilize. Additionally, one of ordinary skill in the art would have been motivated to replace the exemplified alginate with guar gum as both are taught by Burrell et al. as functional equivalents.

It would have been obvious to one of ordinary skill in the art to further add growth factors or surfactants or ethanol to the hydrogel. One of ordinary skill in the art would have been motivated to add any of these ingredients because all are disclosed by Burrell et al. as being suitable ingredients that can be included in the silver containing compositions.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant argues that (1) since the examiner has not clearly determined the level of ordinary skill it is not possible to demonstrate the differences between the claimed invention and the prior art were such that that one would have had a reasonable expectation of success. Applicant argues that (2) the instant claims recite that the hydrogel contains from 5 to 40 ppm silver in the form of colloidal silver particles having a silver interior and a silver oxide exterior and that the proper art is silver coating have only a top layer of silver oxide, therefore the silver oxide of the particles are only on one side. Applicant argues that (3) Burrell et al. teach a wide concentration range of silver and there is little if any demonstration of efficacy within the silver concentration range claimed by applicant. Applicant argues that (4) the silver taught by Burrell et al. is not colloidal silver particles.

Applicant's arguments filed October 8 2009 have been fully considered but they are not persuasive.

The examiner would like to point out that the summary of the Graham factors presented in the Office action can be found in MPEP 2141 (pages 130-132).

Regarding applicant's first argument, the MPEP (2141) indicates that an obviousness rejection can include implicitly an indication of the level of ordinary skill in the art. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007). The prior art teaches a ppm

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range of silver that overlaps that instantly claimed, teaches that guar gum is a suitable hydrocolloid, and growth factors or ethanol can be included. Therefore, all of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. **Note: MPEP 2141 [R-6] KSR International CO. v. Teleflex Inc.** 82 USPQ 2d 1385 (Supreme Court 2007).

Regarding applicant's second argument, the claims as currently written do indicate particles having an interior of elemental silver however they state that the particles have a surface of silver oxide. The examiner interprets this as a portion of the exterior must be of silver oxide; however, there is nothing in claims that limits the exterior of the particles to be only silver oxide. As long as a surface, which could just be the top surface, is silver oxide it would be the limitations of the instant claims. Therefore, the features upon which applicant relies (i.e., an exterior of silver oxide) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicant's third argument, the examiner agrees that Burrell et al. do teach a range of concentration of silver that is suitable. As pointed out by applicant example 1 teaches a concentration of about 66 ppm. Example 4 teaches a concentration of silver of 10 ppm. A concentration of 10 ppm gave a reduction in viable *P. acne* counts. Therefore, while Burrell et al. do not specifically state the concentration

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of the silver in the gels, Burrell et al. clearly teaches that the lower limit of the range generally taught is efficacious.

Regarding applicant's fourth argument, the gels taught by Burrell et al. are either combined with or the fibers are coated with the silver. The silver taught in these gels is either nanocrystalline silver or silver powder. The nanocrystalline and powder terms are defined by Burrell et al. Nanocrystalline are polycrystals that have a grain size less than 100 nm. Powders are particulates of the metal ranging from less than 100 nm (nanocrystalline) or less than 100 micrometers (paragraphs 0089 and 0090). Gels are indicated as being an admixture of the nanocrystalline metal in admixture with gelling agents (paragraph 0161). Therefore, it is unclear how these are not colloidal particles.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Schonfeld et al. (US Patent No. 4646730).

Applicant Claims

Applicant further comprises hydrogen peroxide. The concentration is between about 1 % wgt/v and about 3.0% wgt/v.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Burrell et al. are set forth above. Specifically, Burrell et al. discloses silver containing hydrogels.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Burrell et al. do not specify that hydrogen peroxide can be added to the silver containing hydrogel. However, this deficiency is cured by Schonfeld et al.

Schonfeld et al. is directed to color stabilized hydrogel dressing. Schonfeld discloses that hydrogen peroxide can be added to a silver containing hydrogel as a color stabilizing agent (column 2 lines 60-61). The amount of hydrogen peroxide is from about 0.25 to 1 % of the total weight of the gel (column 3, lines 50-53).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Burrell et al. and Schonfeld and utilize hydrogen peroxide. One of ordinary skill in the art would have been motivated to utilize hydrogen peroxide in order to provide color stabilization of a hydrogel as taught by Schonfeld et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant argues that (1) adding hydrogen peroxide can produce synergistic antimicrobial results. Applicant argues that (2) that Schonfeld et al. is not concerned with synergistic antimicrobial effect and there is no teaching in Schonfeld et al. that hydrogen peroxide contributes to the efficacy of the gel. Applicant argues that (3) there

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is no teaching that the hydrogen peroxide is effective to reduce color in the absence of magnesium trisilicate and that applicant's gel does not contain magnesium trisilicate.

Applicant argues that (4) neither applicant's gel nor Burrell et al. show any discoloration.

Applicant's arguments filed October 9 2008 have been fully considered but they are not persuasive.

Regarding applicant's first argument, the examiner cannot find these synergistic results in the instant specification. For example, paragraphs 169 and 170 of the instant specification compare the antimicrobial effect of a 22 ppm silver composition with and without hydrogen peroxide. The difference in efficacy is not synergistic.

Regarding applicant's second argument, the fact that applicant has recognized another advantage (that hydrogen peroxide contributes to the efficacy of the gel) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding applicant's third argument, the open language of the instant application would not preclude magnesium trisilicate from being added to the gel. Therefore, just because the claimed invention does not include magnesium trisilicate does not prevent it from being present in the prior art and for that prior art to still render the instant invention obvious.

Regarding applicant's fourth argument, discoloration is taught by Schonfeld et al. as occurring in hydrogel dressings with silver. Burrell et al. does not comment on color stability or discoloration, therefore, Burrell et al. is silent as to any discoloration.

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Therefore, while Burrell et al. may be silent, it was known in the art that discoloration does occur with silver containing hydrogels which would provide motivation to one of ordinary skill in the art to add hydrogen peroxide in order to maintain the color stability of the hydrogel.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-10, 18-24 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of

U.S. Patent No. 7135195 in view of Burrell et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver of between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide wherein the composition manifest antimicrobial properties.

Patent '195 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015 micrometers. The composition exhibits antimicrobial properties. Patent '195 claims all the instant limitations in the dependent claims.

Patent '195 does not claim that the composition comprises a hydrophilic polymer and is in the form of a hydrogel. However, this deficiency is cured by Burrell et al. discloses that formulations of silver that are used to treat skin diseases like acne include hydrogels. The polymers utilized to create hydrogels include alginates, guar gum, and cellulose and derivatives (paragraphs 0154-0156 and 0220).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '195 and Burrell et al. and formulate the composition of Patent '195 into a hydrogel. One of ordinary skill in the art would have been motivated to use this

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type of formulation because both Patent '195 and Burrell et al. are directed to utilizing silver containing compositions for the treatment of various anti-microbial diseases. The treatment of skin diseases such as acne would benefit from a topical application such as a hydrogel. Therefore, when utilizing the silver composition of Patent '195 for the treatment of acne one of ordinary skill in the art would have been motivated to formulate the composition into a hydrogel for easier application to the infected area.

Claims 1-4, 6-10, 18-24 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 118134081. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims are set forth above.

Copending '081 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015 micrometers. The composition exhibits antimicrobial properties. A further limitation is that the composition comprises hydrogel formed by dissolved a hydrophilic polymer into the composition of silver in water. Copending '081 claims all the instant limitations in the dependent claims.

Therefore, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The rejections are maintained since applicant has not made any substantive arguments traversing the rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616